32. (Currently amended) A method of administering a pharmaceutical composition according to claim 1, comprising preparing the pharmaceutical composition comprising of S-tofisopam, pro-drug or pharmaceutically acceptable salt thereof and administering the pharmaceutical composition at a dose of less than 30 mg/kg.

REMARKS

Applicants request acceptance of the claims of the present application in view of the above amendments and the following remarks.

OBJECTIONS

As requested by the Examiner, Applicants have amended claim 32 so that claim 32 is a method of administration claim describing the dose at which a pharmaceutical composition comprising S-tofisopam is being administered.

REJECTIONS

Claims 1-5, 28 and 29 have been rejected under 35 U.S.C. 102(a) as being anticipated by the Landry et al

reference. The Landry reference teaches the use of (R)-tofisopam for the prevention and treatment of anxiety and anxiety disorders. (R)-tofisopam was found to be the active isomer of racemic tofisopam in the head twitch assay described in column 21, lines 24-34. (S)-tofisopam was used in the assay merely to show that the (S)-enantiomer was inactive in the assay. Thus, the Landry reference does not anticipate the present invention which describes (S)-tofisopam as an active pharmaceutical ingredient which can be used to effectively treat a disease.

The claims have been further amended to include the limitation that the composition that is being envisioned is one that is pharmaceutically active, rather than a composition that is not pharmaceutically effective.

Furthermore, claim 29 has been amended to delete the language "approximately". None of these amendments introduces new matter.

Double Patenting Rejections

The Examiner has provisionally rejected claims 1-5 and 28-32 under the judicially created doctrine of obviousness-

26. (Canceled) The method according to claim 12 or 13 wherein said amount is administered in 1 to 4 doses per day.

27. (Canceled) The method according to claim 26 wherein said amount is administered in 1 to 2 doses per day.

28. (Currently amended) The pharmaceutical composition according to claim 1, wherein the composition is for intraperitoneal, subcutaneous, intranasal, intramuscular, intrathecal, sublingual, rectal, intravenous infusion, transdermal delivery or oral administration.

29. (Currently amended) The pharmaceutical composition according to claim 1, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from ~~approximately~~ 10 mg to 1200 mg.

30. (Currently amended) The pharmaceutical composition according to claim 1, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.

31. (Currently amended) The pharmaceutical composition according to claim 1, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 100 mg to 400 mg.

32. (Currently amended) A method of administering a pharmaceutical composition according to claim 1, ~~wherein the amount of~~ comprising preparing the pharmaceutical composition comprising S-tofisopam, pro-drug or pharmaceutically acceptable salt ~~administered is~~ thereof and a pharmaceutically effective carrier and administering the pharmaceutical composition at a dose of less than 30 mg/kg.

type double patenting as being unpatentable over claim 31 of copending Application No. 10/781,422. Applicants have submitted a terminal disclaimer to obviate the rejection in the previous response filed 11/29/04.

The Examiner has nonprovisionally rejected claims 1-5 and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of US Patent No. 6,649,607. Applicants have submitted a terminal disclaimer to obviate the rejection in the previous response filed 11/29/04.

Applicants kindly request that the claims be accepted in view of the remarks and amendments provided above.

Respectfully submitted,

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CLAIMS WITH MARKUPS

1. (Currently amended) A pharmaceutical composition comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier.

2. (Currently amended) The pharmaceutical composition of claim 1 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 85% or more by weight of the total weight of tofisopam.

3. (Currently amended) The pharmaceutical composition of claim 1 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 90% or more by weight of the total weight of tofisopam.

4. (Currently amended) The pharmaceutical composition of claim 1 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 95% or more by weight of the total weight of tofisopam.

5. (Currently amended) The pharmaceutical composition of claim 1 wherein the amound of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 99% or more by weight of the total weight of tofisopam.

6. (Canceled) The composition according to claim 1, wherein the conformation of the S-tofisopam is 80% (-) and 20% (+).

7. (Canceled) The composition according to claim 1 further comprising another anti-convulsant.

8. (Canceled) The composition according to claim 7, wherein the other anti-convulsant is a benzodiazepine.

9. (Canceled) The composition according to claim 7, wherein the other anti-convulsant is a 1,4-benzodiazepine.

10. (Canceled) The composition according to claim 7, wherein the other anti-convulsant is selected from the group consisting of diazepam, lorazepam, clonazepam, clorazepate and nitrazepam.

11. (Canceled) The composition according to claim 1, wherein said composition is a controlled-release pharmaceutical composition.

12. (Canceled) A method of treating convulsions or seizures comprising administering to a subject in need of treatment therefore, a therapeutically effective amount of the composition of claim 1.

13. (Canceled) A method of preventing convulsions or seizures in a subject at risk for developing convulsions or seizures comprising administering to a subject in need of treatment therefore, a therapeutically effective amount of the composition of claim 1.

14. (Canceled) The method according to claim 12 or 13 wherein the subject is a human.

15. (Canceled) The method according to claim 12 or 13 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 90% or more by weight of the total weight of tofisopam.

16. (Canceled) The method according to claim 12 or 13 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 95% or more by weight of the total weight of tofisopam.

17. (Canceled) The method according to claim 12 or 13 wherein the amount of S-tofisopam or a prodrug or a pharmaceutically acceptable salt thereof is 99% or more by weight of the total weight of tofisopam.

18. (Canceled) The method according to claim 12 or 13, wherein the composition according to claim 1 is administered together or sequentially with another anticonvulsant.

19. (Canceled) The method according to claim 18, wherein the other anti-convulsant is a benzodiazepine.

20. (Canceled) The method according to claim 18, wherein the other anti-convulsant is a 1,4-benzodiazepine.

21. (Canceled) The method according to claim 18, wherein the other anti-convulsant is selected from the group

consisting of diazepam, lorazepam, clonazepam, clorazepate and nitrazepam.

22. (Canceled) The method according to claim 12 or 13, wherein the composition is administered intraperitonealy, subcutaneously, intranasally, intramuscularly, intrathecaly, sublingualy, rectally, by intravenous infusion, transdermal delivery or orally as a tablet, a capsule or a liquid suspension.

23. (Canceled) The method according to claim 12 or 13, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof administered is from approximately 10 mg to 1200 mg.

24. (Canceled) The method according to claim 23 wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof administered is from approximately 50 mg to 600 mg.

25. (Canceled) The method according to claim 23 wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof administered is from approximately 100 mg to 400 mg.